# AMICUS CURIAE

# BRIEF

(18)

No. 90-1038

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1991

THOMAS CIPOLLONE,

*Petitioner,*

*v.*

LIGGETT GROUP, INC., *et al.*,

*Respondents.*

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

## BRIEF OF THE NATIONAL ASSOCIATION OF MANUFACTURERS AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

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### INTEREST OF THE AMICUS CURIAE

The National Association of Manufacturers of the United States of America ("NAM") is a voluntary business association of approximately 12,500 companies and subsidiaries, employing eighty-five percent of all manufacturing workers and producing over eighty percent of the nation's manufactured goods. More than 158,000 additional businesses are affiliated with NAM through its Associations Council and National Industrial Council. NAM and these councils are vitally interested in a balanced and proper interpretation of the scope of preemption language in federal statutes. Letters of consent from the parties permitting the filing of this brief have been filed with the Clerk of the Court.

## SUMMARY OF THE ARGUMENT

The Third Circuit correctly held that the Federal Cigarette Labeling and Advertising Act ("Cigarette Act"), 15 U.S.C. §§ 1331 *et seq.*, preempts common law duty to warn claims,[1] but it erred in finding preemption merely to be implied. The express preemption provision of the Act unambiguously removes all state authority to require that statements relating to smoking and health, other than those prescribed by Congress, appear on cigarette packaging. Because state common law tort actions have a clear regulatory effect on the conduct of manufacturers with regard to warnings, such actions fall squarely within the scope of the express preemption provision of the Cigarette Act.

Even if this Court were not to find express preemption, it should affirm the Third Circuit on the ground that preemption is implied. A direct, actual conflict exists between the federal purpose underlying the Act and the effect of state tort actions for failure to warn. Congress intended the uniform warnings required by the Act to facilitate interstate commerce and protect against diverse warnings. Common law actions in state courts would inevitably impose a hodgepodge of additional warning requirements. If manufacturers attempt, as they must, to respond by changing their warning labels, or by disseminating additional information through other means, Congress' stated goal of ensuring nonconfusing and nationally uniform warnings would be defeated.

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1 The interest of *amicus* in this case largely concerns the mistaken views on the law of preemption that have been adopted by the Petitioner and his *amici* and the courts in *Dewey* v. *R.J. Reynolds Tobacco Co.*, 121 N.J. 69, 577 A.2d 1239 (1990) and *Carlisle* v. *Philip Morris, Inc.*, 805 S.W.2d 498 (Tex. Ct. App. 1991). We believe that the error of these views can be demonstrated through analysis of the Cigarette Act's preemptive effect on failure to warn claims. There is, therefore, no need to discuss separately the issues concerning preemption of claims based upon the propriety of Respondents' advertising. We note, however, our full agreement with Respondents' interpretation of the Cigarette Act with regard to the preemption of such claims. By clearly providing that no requirements or prohibitions relating to smoking and health may be imposed by the states with respect to the labeling, advertising, or promotion of cigarettes, the statute preempts not merely actions for the things that cigarette manufacturers have not said about smoking and health (i.e., claims alleging failure to warn) but also suits for what they have communicated (e.g., claims alleging misrepresentation).



Finally, this Court should reject Petitioner's invitation to adopt a broad and inflexible rule that preemption cannot occur unless either Congress expresses its intent "with drastic clarity" or there is no sense, however farfetched, in which state and federal law can coexist. Such a rigid approach would require the Court to abandon its long-established and highly appropriate practice of deciding preemption questions by fact-specific inquiries into the purpose, structure, and language of particular pieces of legislation and particular conflicts between state and federal law.

## ARGUMENT

### I. CONGRESS HAS PREEMPTED STATE COMMON LAW CLAIMS RELATING TO HEALTH WARNINGS

#### A. The Cigarette Act Expressly Preempts Any State Action That Results In A Warning Requirement Relating To Smoking And Health.

The Third Circuit correctly found that the Cigarette Act preempts state tort actions for failure to warn. The *amicus* differs with the Third Circuit on this point in only one respect: we believe, in contrast to the court below, that the statute should be found to preempt such actions expressly. This does not mean that the courts that have found implied preemption were incorrect in discerning an actual conflict between state tort actions based on the alleged inadequacy of the health information provided by the cigarette manufacturers and the federal purposes underlying the Cigarette Act—but merely that tort requirements with respect to warnings also fall within the scope of the express preemption provision. We urge this Court to find that Congress expressed its expectation directly in the language it chose for the preemption clause: a tort remedy *is* preempted because it is a form of prohibited requirement.

The court below confused the analysis of this question because it assumed that Congress, if it wished to preempt state tort remedies directly, would have done so using specific rather than general terms—that is, by actually specifying that states could not use tort

actions as a method of frustrating the purpose of the Act. But the express preemption in this statute was accomplished in a different way. Congress, rather, chose to address preemption comprehensively, prohibiting other warning requirements relating to smoking and health regardless of how or by whom such requirements might be imposed. 15 U.S.C. § 1334(a).[2] Because Congress made absolutely clear that it wished to preempt state-imposed warning requirements, the only question this Court must decide, to determine this aspect of the case, is whether tort remedies based on failure to warn are a form of requirement. If they are, and we argue that this point is incontrovertible, then it is respectfully submitted that the Court must find express preemption in this case.

A presumption against preemption was used by the court below as a reason to demand specific language addressing tort remedies in order to find express preemption. This reasoning was incorrect. The presumption against preemption supports the interests of federalism by providing a rule of decision for cases where it is a close question whether or not Congress intended to displace state authority. It is not an arbitrary stricture meant to disfavor particular *means* for evincing that intent. The lower court's approach imposes on Congress an unjustifiably rigid standard for the drafting of statutes. If that analysis is upheld, Congress will be able to achieve express preemption in only one way—by spelling out in great detail every specific act that is prohibited—whereas it can impliedly preempt exactly the same activity simply by the general way in which an act is structured. Such a rule erects unjustified and artificial barriers to permitting the express intent of Congress to be credited by the courts. It should be rejected.[3]

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[2] The text of this section is set out in the Statutory Appendix (Stat. App.) at A-1.

[3] By contrast, a very different treatment has been accorded similar language in another statute. The Medical Device Amendments of 1976, 21 U.S.C. §§ 360c *et seq.*, contain a preemption provision worded much like that in the Cigarette Act. *See* 21 U.S.C. § 360k(a) (text set out in Stat. App. at A-1). The preemptive effect of this statute has been widely tested in the courts below, largely in cases of toxic shock attributed to tampon use. The Act has almost always been held to preempt tort actions for failure to warn, and in several instances, the courts have found that intent to have been directly expressed by Congress in § 360k(a). *See, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 247 (5th Cir. 1989); *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475, 477 (S.D. Ind. 1988); *Stewart v. International Playtex, Inc.*, 672 F. Supp. 907, 909 (D.S.C. 1987); *Berger v. Personal Prods., Inc.*, 115 Wash. 2d 267, 275, 797 P.2d 1148, 1152 (1990), *cert. denied*, 111 S. Ct. 1584 (1991). Nothing in the opinions reveals a reason to find express preemption in this language and not to find it in the similar "requirement" language of the Cigarette Act.



While it is true that, in certain circumstances, Congress has used both preemption and savings clauses that identify specific actors or types of actions,[4] there is certainly no rule that Congress can only draft statutes in one way. Congress is entirely free to adopt any form of words it chooses to accomplish its purposes, including drafting a preemption provision, as it has here, that identifies a *result*, rather than a specific form of action, it wishes to prevent.

The advantage of identifying the desired result is obvious: it allows Congress to achieve its objective without having to predict in advance every possible circumstance under which an exercise of state authority could defeat or distort its aims. That this was the path Congress took in the Cigarette Act has been implicitly acknowledged by the courts below. It is quite evident that the very presence of the broadly couched preemption clause here at issue is a major reason preemption of state tort actions by the Cigarette Act has been so widely recognized by both state and federal courts. *See, e.g., Cipollone v. Liggett Group, Inc.*, 789 F.2d 181, 186 (3d Cir. 1986) (broad language of preemption clause one piece of evidence relied upon to find implied preemption), *cert. denied*, 479 U.S. 1043 (1987).

A reason why it is advantageous to allow Congress to target a result rather than specific means is that Congress cannot always predict how the law will develop. This fact is demonstrated by the historical context of the Act. The Cigarette Act was first passed at a time of great ferment. State and local authorities as well as federal administrative agencies had been galvanized by the 1964 Surgeon General's Report on Smoking and Health into looking for ways to

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[4] For example, the Consumer Product Safety Act of 1972 requires nationwide compliance with federal safety standards but specifies that such compliance is not a defense to liability under state statutory or common law. 15 U.S.C. § 2074. Similarly, Congress included a savings provision for tort liability arising under either state statutes or common law in the Comprehensive Smokeless Tobacco Health Education Act of 1986. 15 U.S.C. § 4406(c). *See* pp.13–15, *infra*.

regulate the tobacco industry and educate consumers on the risks of smoking. *See* H.R. REP. NO. 449, 89th Cong., 1st Sess., *reprinted in* 1965 U.S. Code Cong. & Admin. News 2350, 2351-53. State tort law was also in a period of change. The first important decision applying the doctrine of strict tort liability to a personal injury action arising from a defective product had been handed down only two years before. *Greenman v. Yuba Power Prods., Inc.*, 59 Cal.2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963). Section 402A of the Restatement (Second) of Torts, a strict liability formulation subsequently adopted by most states for analyzing product liability claims, was working its way through the process of adoption by the American Law Institute in the period immediately preceding the passage in 1965 of the original version of the Cigarette Act.

In the face of so much and such varied activity, it is little wonder that Congress did not feel compelled (or perhaps able) either in 1965, when it wrote the preemption provision, or in 1969, when it amended it, to predict every specific sort of activity that conflicts with its objectives.[5] Nor should it be required to do so. Rather it chose to speak in terms of preempting state requirements. With respect to tort judgments based on failure to warn, the relevant question, therefore, is simply whether such judgments are a form of requirement. If so, then they have been expressly preempted.

5 Petitioner cites to certain colloquies that occurred during consideration of the 1965 Cigarette Act and the 1969 amendments to support his claim that Congress did not intend tort actions to be within the reach of the preemption provision. *See* Brief for Petitioner at 33-36, nn. 41, 42. The most that can be said for these bits of debate is that they suggest that some members of Congress believed that at least some tort claims for personal injury would survive the passage of the Act. A decision by this Court to affirm *Cipollone*, which finds preemption as to some but not all of Petitioner's claims, would in no way be inconsistent with that understanding. The discussions do not suggest that those members of Congress had thought very deeply about the possible impacts of tort law on its legislative scheme, but they certainly do not evince a willingness to have the objective of a uniform national system of warnings undercut by diverse judge- or jury-made rules. Because legislative history must be used cautiously, *see Piper v. Chris-Craft Industries, Inc.*, 430 U.S. 1, 26 (1977), and because colloquies like these are among the least reliable forms of legislative history, *see Garcia v. United States*, 469 U.S. 70, 76 (1984); *United States v. O'Brien*, 391 U.S. 367, 385 (1968), this Court should not give undue weight to these passages as evidence which contradicts the express language, purpose and structure of the Act. The text itself provides the clearest, most reliable evidence of what Congress intended to achieve.



### 1. State Tort Remedies Based On Failure To Warn Have A Regulatory Effect And Are, Therefore, A Form Of Prohibited Requirement.

Petitioner and his *amici* say that there is no express preemption under the Cigarette Act because tort judgments are not a form of requirement. Their argument is naive, and ultimately self-contradictory. They attempt to downplay the regulatory nature of tort verdicts for failure to warn by claiming that tort actions primarily compensate victims and affect the future behavior of defendants at most indirectly, and often not at all. They suggest that a verdict in favor of a plaintiff cannot be a requirement because such a verdict lacks the compulsory effect of a state statute or regulation. The defendant, according to this argument, can decide not to change its behavior but can instead simply opt to pay. This argument is wrongheaded for many reasons,[6] but in particular because it ignores altogether the peculiar nature of failure to warn claims involving mass-produced products.

Although some might argue that tort actions for ordinary negligent injury are primarily compensatory and only incidentally regulatory, the same could not be said for failure to warn claims in product cases. A traffic accident may occur in hundreds of ways, and—fortunately for all of us—it will be a rare driver who causes

6 The argument that tort judgments do not regulate because the defendant has a choice simply to pay money is no more convincing than the same argument would be if applied to a criminal fine. In those cases, too, the defendant need not change his behavior, but can simply pay. That fact alone does not mean that criminal law is not regulatory. Nor can it be argued that criminal fines are different because, if the wrongdoer persists in his misconduct, the penalty will be increased. The same is true in the tort system. A manufacturer who pays a failure-to-warn judgment without modifying its subsequent behavior exposes itself to punitive damages in later cases; a refusal to change its behavior becomes evidence of willful and wanton misconduct or reckless disregard of safety that justifies exemplary damages. *See, e.g., Sturm, Ruger & Co. v. Day*, 594 P.2d 38, 47 (Alaska 1979) (punitive damages a way to insure that manufacturer cannot opt merely to pay), *modified*, 615 P.2d 621 (1980), *cert. denied*, 454 U.S. 894 (1981). This fact is conveniently ignored by Petitioner and his amici in making their argument that tort remedies are not compulsory.

them repeatedly and each time in precisely the same fashion. Thus, a successful suit against a careless driver will be quite fact-specific, and although it will hopefully encourage that person to take greater care in the future, it could be argued that the primary function of the verdict is to provide a particular victim with compensation.

In contrast to the defendant whose momentary carelessness causes an isolated accident, a product manufacturer or distributor who breaches its duty to warn exposes every consumer of the product to a similar potential risk; the manufacturer's course of conduct that leads to Consumer A's injury is indistinguishable from that which injures Consumers B and C. At least as important as the compensation of the victim, therefore, is the impetus provided by the threat of repeated damage awards against a manufacturer or a seller of consumer goods with the capacity to inflict similar harm on numerous users.

An even more extreme manifestation of the regulatory objective of products liability litigation is found in the availability of punitive damages for failure to warn. *See, e.g., Jackson v. Johns-Manville Sales Corp.*, 781 F.2d 394, 399-407 (5th Cir.), *cert. denied*, 478 U.S. 1022 (1986) (punitive damages available for failure to warn); *Tetuan v. A.H. Robins Co.*, 241 Kan. 441, 738 P.2d 1210 (1987) (same); *Palmer v. A.H. Robins Co.*, 684 P.2d 187 (Colo. 1984) (same). Awards of punitive damages are well recognized to be for the purpose of "teaching the defendant not to do it again, and of deterring others from following the defendant's example." W. KEETON, D. DOBBS, R. KEETON, & D. OWEN, PROSSER AND KEETON ON TORTS 9 (5th ed. 1984).

This reality clearly explains the argument against preemption made in the *amicus* brief submitted on behalf of twelve states, which contradicts Petitioner's claim that tort damage judgments do not regulate. These states urge that *Cipollone* be reversed precisely because products liability tort actions in fact *do* regulate. They argue that the states should be permitted to retain authority to promulgate tort rules in this area because such rules act as a prophylactic against future harm. As the states recognize, tort actions



> [encourage] manufacturers to produce a safer product and design better consumer warnings regarding the dangers of cigarette smoking . . . . Thus, state common law is an additional tool, complementary to statutory enactments, to minimize the harmful health effects of cigarette smoking on their citizens.

Brief *Amici Curiae* of the State of Minnesota, *et al.*, in Support of Petitioner at 6.

We believe that the states are clearly correct in their evaluation of the effect of tort rules. Where we part company with them, however, is on the conclusion they draw from their observation. In their brief, the states express a desire for authority to regulate in the area of warnings through operation of their tort rules. This is just the authority that Congress has denied them. The fact that the states disagree with this decision does not change the fact that Congress was entitled to make it, and did.

That tort actions can have the effect of a regulatory requirement has been well-recognized by this Court, a fact which could not have been entirely beyond the ken of Congress when it drafted the earliest version of the Act in 1965. Six years before, in *San Diego Building Trades Council v. Garmon*, 359 U.S. 236 (1959), this Court had found state tort actions to be a preempted form of regulation. The opinion stated clearly that "[R]egulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy". *Id.* at 247. And in 1964 in the landmark defamation case, *New York Times Co. v. Sullivan*, this Court observed that, "The fear of damage awards . . . may be markedly more inhibiting than the fear of prosecution under a criminal statute." 376 U.S. 254, 277 (1964).

Later decisions have also acknowledged that common law rules can regulate in ways that conflict with federal statutes and regulations. *See, e.g., International Paper Co. v. Ouellette*, 479 U.S. 481, 494-95 (1987) (state common law nuisance actions are a form of conflicting regulation and preempted to the extent that they contravene the federal water pollution control scheme); *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S.

311, 323-27 (1981) (state actions for common law negligence and interference with contractual relations a form of regulation preempted by the Interstate Commerce Act).

Although the decision in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), is heavily relied upon by the Petitioner, as well as by the District Court in the first *Cipollone* ruling, to support a finding that common law remedies are not preempted by the Cigarette Act, *Silkwood* does not in any sense stand for the proposition that a requirement imposed by common law is not a "real" requirement for preemption purposes. In fact, this Court specifically acknowledged in *Silkwood* that liability for damages is a form of regulation. *Id.* at 256.

**2. Congress Followed The Cigarette Act Model In Drafting A Later Preemption Provision And Did So With Full Knowledge Of The Preemptive Effect Given That Language By The Federal Circuits.**

An additional source of insight into the meaning of the Cigarette Act's preemption clause can be gained by an examination of what Congress did in drafting subsequent legislation. As this Court has acknowledged elsewhere, other legislation containing similar provisions can sometimes shed light on Congress' intent with regard to preemption. *See, e.g., Ingersoll-Rand Co. v. McLendon*, 111 S. Ct. 478, 485-86 (1990) (finding parallels between ERISA and the Labor Management Relations Act with regard to preemption). In this case, two statutes, both involving warnings and both passed at a time when Congress was clearly aware that courts were beginning to examine whether tort actions were preempted by a variety of federal statutory schemes, provide support for the argument that the preemption clause in the Cigarette Act covers tort actions rooted in failure to warn. Those statutes are the Alcoholic Beverage Labeling Act of 1988 ("Alcohol Act"), 27 U.S.C. §§ 213 *et seq.*, and the Comprehensive Smokeless Tobacco Health Education Act of 1986 ("Smokeless Tobacco Act"), 15 U.S.C. §§ 4401 *et seq.*



The Alcohol Act is instructive because it parallels the Cigarette Act in important regards.[7] Like the Cigarette Act, it starts with a statement of purpose and policy. 27 U.S.C. § 213.[8] Although somewhat more detailed than the equivalent provision in the Cigarette Act, 15 U.S.C. § 1331, it states a similar intent to strike a balance between the public's need for information about health risks and the need to protect "commerce and the national economy." In both statutes, Congress itself dictates the contents of the required warnings.[9] The Alcohol Act, like the Cigarette Act, also contains a broadly-worded preemption provision. 27 U.S.C. § 216. Using language very similar to that in the Cigarette Act, the Alcohol Act provides that "[n]o statement relating to alcoholic beverages and health, other than the statement required by [this Act], shall be required under State law" on any container or box or other packaging of alcoholic beverages.[10]

There is strong evidence that use in the Alcohol Act of the same kind of preemption provision used in the Cigarette Act was thought by its drafters also to preclude state tort actions for failure to warn. In the original version of S. 2047, the bill that ultimately became the Alcohol Act, a savings clause had been inserted which said that:

> Nothing in this section shall be construed to relieve any person from any liability under Federal or State law to any other person.

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7 The most significant difference is that the Alcohol Act is limited to warnings on beverage containers and packaging; the Act does not address advertising.

8 Section 213 is set out in Stat. App. at A-1.

9 *Compare* 15 U.S.C. § 1333 *with* 27 U.S.C. § 215(a).

10 The Alcohol Act defines "state law" to include "statutes, regulations, and principles and rules having the force of law." 27 U.S.C. § 214 (11). This definition is consistent with the numerous court opinions that have held that the terms "law" or "state law" include common law rules, *see, e.g., Norfolk & W. R. Co. v. Train Dispatchers*, 111 S. Ct. 1156, 1163 (1991); *Illinois v. City of Milwaukee*, 406 U.S. 91, 100 (1972); *Erie R. Co. v. Tompkins*, 304 U.S. 64, 71, 79 (1938), and with the definition of "state law" in other federal statutes. *See, e.g.*, 29 U.S.C. § 1144(c)(1) (ERISA) (defining "state law" to include "laws, decisions, rules, regulations, or other State action having the effect of law"). There is no reason to

S. 2047(g), *reprinted in Alcohol Warning Labels: Hearing Before the Subcommittee on the Consumer of the Sen. Comm. on Commerce, Science, and Transportation*, 100th Cong., 2d Sess. 4, 10 (1988). The bill was subsequently amended to replace a lengthy series of findings on the health consequences of alcohol use and abuse with the current Declaration of Policy and Purpose, focusing (as does the equivalent provision of the Cigarette Act) on balancing economic and health goals. In addition, the savings clause was eliminated and, in its place, the broad preemption provision noted above was added.

This history suggests that, as the purpose of the legislation changed from a purely public health measure to an accommodation between economic and health concerns, Congress dropped the savings clause for the express purpose of precluding those state tort actions that endanger the accommodation.[11] It would seem odd indeed for Congress to use virtually the same language in the Alcohol Act that it did in the Cigarette Act while anticipating that one provision would be interpreted to preempt all inconsistent state actions including tort remedies and that the other would not.

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believe Congress meant the term "state law" in the Cigarette Act, 15 U.S.C. § 1334(b), where it is undefined, to have any different meaning.

11 Although comments during floor debate should be used cautiously in determining congressional intent, the discussion of preemption prior to enactment of the Alcohol Act lends further credence to the view that Congress intended the Act to displace state tort actions. In describing the legislation to the Senate immediately prior to its passage, Senator Ford stated:

> One of the most difficult provisions to reach agreement on in this measure was the preemption language of section 205 [27 U.S.C. § 216]. This section was critical to the success of the negotiations and to my support of it. * * * In an attempt to minimize the burden on what is a legitimate and responsible industry, the preemption provisions of this act avoid what could otherwise be a multitude of inconsistent statutes, regulations, *and common law rules*. . . . It is my understanding that this section is to be [read] and administered so as to preclude any State or local authority, through legislation, regulation, *or judicial interpretation*, from requiring a different warning [label] on beverage alcohol containers. We intend that Congress exclusively reserve the power to consider whether, due to future developments or other considerations, any additional or differential warnings will be required on beverage alcohol containers.

134 CONG. REC. S17301 (daily ed. Oct. 21, 1988) (emphasis added). Similarly, just prior to House passage of the Act, Representative Coehlo told his colleagues:



Furthermore, Congress followed the Cigarette Act model in the face of a consensus of court decisions finding the Cigarette Act to preempt duty to warn actions. At the time the Alcohol Act was passed late in 1988, every federal Court of Appeals that had considered the issue had found state tort law to be preempted by the Cigarette Act. *See Roysdon v. R.J. Reynolds Tobacco Co.*, 849 F.2d 230 (6th Cir. 1988); *Palmer v. Liggett Group, Inc.*, 825 F.2d 620 (1st Cir. 1987); *Stephen v. American Brands, Inc.*, 825 F.2d 312 (11th Cir. 1987); *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181 (3d Cir. 1986), *cert. denied*, 479 U.S. 1043 (1987). Congress' use of almost identical statutory language in the face of these highly publicized judicial interpretations arguably evinces agreement with the result reached by the courts.[12]

The Smokeless Tobacco Act, 15 U.S.C. § 4401 *et seq.*, presents a telling contrast. Like the Cigarette and Alcohol Acts, the Smokeless Tobacco Act also sets out the text of the required warning, *id.* § 4402. The statute has a preemption provision that prohib-

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> To avoid a crazy quilt of inconsistent statutes, regulations *and common law rules* that would subject alcoholic beverages to intolerable burdens, section 205 [27 U.S.C. § 216] makes clear that under the act the power to regulate the labeling of alcoholic beverages to achieve public health objectives rests exclusively with the Congress.

134 CONG. REC. H11250 (daily ed. Oct. 21, 1988) (emphasis added). Contrary statements, denying an intent to preempt tort law, were inserted into the record by two Congressmen *after* the statute was enacted, *see* 134 CONG. REC. E3764 (daily ed. Nov. 10, 1988) (statement of Rep. Conyers); *id.* at E3729 (statement of Rep. Waxman). Post-enactment statements such as these, however, have little, if any, interpretive value because they were not before Congress at the time it decided whether, and in what form, to pass the legislation. *See, e.g., Pittstown Coal Group v. Sebben*, 488 U.S. 105, 118-119 (1988); *Blanchette v. Connecticut Gen. Ins. Corps.*, 419 U.S. 102, 132 (1974).

12 While the decisions in question found implied rather than express preemption, that distinction was unlikely to have affected Congress' thinking. The main point is that Congress could not have had any significant doubt that its new initiative would be interpreted by the courts as preempting inconsistent tort requirements. For example, during consideration of the Alcohol Act, Senator Harkin inserted an article from *The New Republic* into the Congressional Record. That article discussed the fact that the Cigarette Act had been held in *Cipollone* to prevent recovery for failure to warn and suggested that the pending alcohol labeling legislation would benefit alcoholic beverage manufacturers by similarly protecting them from such suits. 134 CONG. REC. S8821-22 (daily ed. June 29, 1988).

its the requirement of any other statement by "any State or local statute or regulation." *id.* § 4406(b). Unlike the Cigarette and Alcohol Acts, it provides that, "Nothing in this chapter shall relieve any person from liability at common law or under State statutory law to any other person." *Id.* § 4406(c).[13]

This important difference between the Smokeless Tobacco Act and the Cigarette and Alcohol Acts is attributable to the different purposes of the respective sets of laws. The Smokeless Tobacco Act is wholly a public health measure; nowhere on the face of the statute is one word said about balancing health concerns against the competing claims of interstate commerce and the national economy. Indeed, the legislative history of the Act makes abundantly clear that Congress did not have balancing in mind.

The reason is that the economic and health aspects of the equation were, in Congress' view, quite different in the case of smokeless tobacco. First, compared with the cigarette and alcoholic beverage industries, the impact of smokeless tobacco on the national economy was minor. Cigarettes and alcoholic beverages are much larger industries, with spillover effects on many other sectors of the economy. Thus, their fiscal "health" was a legitimate concern of Congress. The House Report on the original Cigarette Act noted that the effects of regulation of health warnings could be felt by "the entire tobacco raising and manufacturing industry, and the numerous businesses which market tobacco products," including "the television, radio, and publishing industries." H.R. REP. NO. 449, 89th Cong., 1st Sess., *reprinted in* 1965 U.S. CODE CONG. & ADMIN. NEWS 2350, 2352. The Senate Report on the Alcohol Act stresses that the choice of a single warning for all beer, wine and spirits is intended "to avoid misleading information and minimize burdens on interstate commerce." S. REP. NO. 100-596, 100th Cong., 2d Sess. 5 (1988). Without reasonable, uniform directions on how to accommodate their business practices to the public need for health information, the cigarette and alcohol industries and associated businesses could suffer considerable financial harm in the form of a tangle of inconsistent local statutes and regulations as well as from the potential for unpredictable and significant tort claims.

13 This is the same language that appeared in the original Senate version of the Alcohol Act, and was later deleted.



Furthermore, because Congress could count on a considerable reservoir of already-existing public knowledge about both alcoholic beverages[14] and cigarettes[15] – which did not, in Congress' view, exist in the case of smokeless tobacco[16] – it was able, responsibly, to balance its desire to provide consumers with clear, non-confusing information on risks, while at the same time preserving for the cigarette and alcohol industries freedom from "a multiplicity of State and local regulations" and "chaotic marketing conditions."[17] It would have made no sense, given the factual circumstances and Congress' *dual* goals, either for Congress to have included a savings

14 Congress recognized when it enacted the Alcohol Act that the public was already very well-informed about risks associated with alcohol consumption and abuse. Comments about the high degree of public awareness of the major health effects of alcoholic beverage abuse appear throughout the legislative history of the Alcohol Act, often supported by references to national polling data. *See, e.g.*, 134 CONG. REC. H11249 (daily ed. Oct 21, 1988) (statement of Rep. Coehlo) (awareness is "nearly universal"); *id.* at S17301 (statement of Sen. Ford) (awareness is "widespread"). As a result, Congress characterized its purpose in requiring the statutory warning as providing a "reminder". 27 U.S.C. § 213.

15 As a result of the enormous publicity surrounding the 1964 Surgeon General's Report on Smoking and Health and the vigorous public education campaign it generated, the House Committee on Interstate and Foreign Commerce observed in 1965 that "many persons . . . already are aware of the smoking and health issue." H.R. REP. NO. 449, *supra,* 1965 U.S. CODE CONG. & ADMIN. NEWS at 2352. The House Report notes that, largely as a result of this publicity, one out of four adult male smokers had given up cigarettes in the previous year. *Id.* In 1964, the year before the passage of the Cigarette Act, 81% of adults agreed that smoking is harmful to health. *Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General* at 179 (DHHS Pub. No. (CDC) 89-8411, 1989).

16 The 1964 Surgeon General's Report launched a national effort to educate the public on the risks associated with cigarette smoking. Congress concluded, however, that an unanticipated outcome of this campaign was to send some consumers in search of a "safe" substitute for cigarettes. Many apparently turned to smokeless tobacco products. According to Congress, the sales of products like snuff and chewing tobacco burgeoned because some were "under the mistaken impression that the use of smokeless tobacco carries no significant risk to health," and was "a safe and healthful alternative to cigarettes." S. REP. NO. 99-209, 99th Cong., 2nd Sess. 4, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 7, 10. The exclusive purpose of the smokeless tobacco legislation, therefore, was to close this perceived information gap.

17 H.R. REP. NO. 449, *supra,* 1965 U.S. CODE CONG. & ADMIN. NEWS at 2352 (Cigarette Act). *See also,* S. REP. NO. 100-596, 100th Cong., 2d Sess. 5 (1988) (Alcohol Act).

clause in this legislation, or to have chosen to tolerate any form of inconsistent state or local regulation of warnings, including that imposed by virtue of tort law.

When all these considerations are taken into account, the conclusion that the preemption language in the Cigarette Act reaches all state requirements relating to warnings is difficult to avoid. Because tort law judgments plainly impose requirements, they fall within the scope of the express preemption clause of the Act.

It is obvious from reading the *amicus* briefs on behalf of Petitioner that, in the case of cigarettes, many fervently disagree with the policy choice made by Congress to compromise between economic and health interests, and that they would like this Court to shift that balance. These sentiments may be widely shared. We respectfully submit, however, that this case is not a referendum on whether cigarettes should continue to be sold, or on whether Congress has found the right balance between health and economic concerns. Those policy questions are for Congress. The only question here is what Congress meant by the express language it used, and we submit that the answer to that question is clear.

### B. Preemption Is Implied From A Direct, Actual Conflict Between The Purposes of Congress And The Effect Of State Tort Actions For Failure To Warn.

Even if this Court were to conclude that tort actions do not fall within the proscriptive ambit of the express preemption provision, the inquiry is not complete.[18] As this Court has said when deciding preemption questions, the "sole task is to ascertain the intent of Congress." *California Fed. Savings & Loan Ass'n v. Guerra*, 479

[18] Petitioner and certain *amici* for Petitioner argue that if the preemption provision in a statute does not expressly cover a particular form of state activity, this Court should end its inquiry. The cases cited for this proposition do not support the simplistic analysis urged by Petitioner. In both *California Fed. Savings & Loan Ass'n v. Guerra*, 479 U.S. 272 (1987), and in *California Coastal Comm'n v. Granite Rock Co.*, 480 U.S. 572 (1987), which are cited for this proposition, the Court in fact engaged in a searching examination of the evidence of Congress' intent before deciding the preemption question. The Court looked at a variety of matters, including the history of the statutes, at other provisions of the acts, and at the



U.S. 272, 280 (1987). If the preemption provision alone supplies insufficient evidence of that intent or if no preemption provision exists, this Court's uniform practice has been to ask whether preemption can be implied from a combination of other indicia of intent. *See, e.g., International Paper Co. v. Ouellette*, 479 U.S. 481, 494-97 (1987) (Court finds partial preemption, despite savings clause, by examining congressional objectives under Clean Water Act).

One reason to find implied preemption is that state law "regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *English v. General Electric Co.*, 110 S.Ct. 2270, 2275 (1990). Another is that state law "actually conflicts with federal law." *Id.* These categories are not entirely discrete, often making it possible to think of the same problem either as one of field preemption or of actual conflict. *Palmer v. Liggett Group, Inc.*, 825 F.2d 620, 624-26 (1st Cir. 1987). Most courts to date have analyzed the Cigarette Act as posing a question of actual conflict. What is most important, however, is that the overwhelming majority of them have found an implied intent to preempt failure to warn actions by examining the face of the Act. The reasons for this will quickly be discerned by the Court.

#### 1. An Intent To Preempt Common Law Tort Remedies Is Implied By The Purpose, Structure And Language Of The Cigarette Act.

The stated purposes of the Act, its structure, and the existence in it of a broad preemption provision all work together to make manifest an intent to settle the question of how cigarette manufacturers are to fulfill their duty to see that consumers are adequately informed about the health hazards associated with their product.

The purpose of the Cigarette Act is set out in 15 U.S.C. § 1331. This section speaks of Congress' intent to "establish a *com-*

possibility of an actual conflict between state and federal authority. Furthermore, in *Jones v. Rath Packing Co.*, 430 U.S. 519, 540-41 (1977), the Court, after failing to find express preemption, went on to conclude that state law was nonetheless impliedly preempted. These decisions evinced no inclination to apply some cut-and-dried summary approach to preemption analysis, and the Court is urged to continue to examine each case rigorously, fully and on its own merits. See pp. 25–29, *infra*.

*prehensive* Federal program to deal with cigarette labeling and advertising with respect to *any relationship between smoking and health*" (emphasis supplied); it then goes on to set out as dual goals the provision of adequate information to the public while at the same time providing protection of "commerce and the national economy" and preventing "diverse, nonuniform, and confusing regulations with respect to any relationship between smoking and health." Clearly, Congress was engaged in a balancing of interests.

In pursuit of the desired balance, Congress dictated the actual wording of the health warning. 15 U.S.C. § 1333. It also added the preemption provisions in § 1334(a) and (b), which prohibit the imposition on manufacturers by the states of any additional requirement with regard to labeling or any prohibition or requirement with regard to advertising or promotion of cigarettes. All of this careful crafting was obviously intended to provide cigarette manufacturers with the considerable business benefit of a dependable, predictable way to fulfill their responsibilities to caution consumers.

Petitioner and his *amici* concede that Congress wanted to displace direct regulatory activity by the states with regard to warnings so that the manufacturers, and the nation's economy, could enjoy the benefits of this scheme. In effect, however, they argue that Congress was perfectly willing to see its carefully crafted compromise undone by the regulatory effect of common law tort actions imposing, on an *ad hoc* basis, a hodgepodge of additional requirements. This argument is absurd on its face, and it is little wonder that very few courts have accepted it. The handful of courts that have rejected preemption seem to have based their decisions more on a dislike for Congress' choice of policy than on a sound, objective preemption analysis. We suggest that this Court need look no further than the face of this statute—at what Congress said about its intent and expectations—to decide that the law does indeed preempt tort actions relating to health warnings.

**2. The Arguments Against Implied Preemption Are Not Persuasive.**

**(a) Preemption Should Not Be Denied Simply Because Congress Has Provided No Alternative Remedy.**

Petitioner relies heavily on this Court's decision in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), for the proposition that



the presumption against preemption should be applied with special rigor in cases where individuals would otherwise be deprived of traditional state tort remedies. Petitioner cites to language in Justice Blackmun's dissent that, out of context, seems to support that argument. 464 U.S. at 263-64. But the reason that state tort actions were not found to be preempted in *Silkwood* turns out upon examination to have been on quite different grounds.

The Atomic Energy Act of 1954, 42 U.S.C. §§ 2011 *et seq.*, was designed by Congress to place the safety regulation of nuclear facilities in the hands of the federal government. The Act was, however, silent on the subject of remedies for individuals injured by radiation from such facilities. When this Court examined all the evidence surrounding the Act, however, it found clear indication that Congress had no intention of displacing the right of injured persons to recover under state tort law. This evidence was supplied by a subsequent amendment to the Act, the 1957 Price-Anderson Act, Pub. L. 85-256, 71 Stat. 576. The Price-Anderson Act set a ceiling on the aggregate amount of damage awards that could be imposed on a facility for a single nuclear incident; from this, the Court not surprisingly inferred that Congress had intended state tort remedies to be unaffected when it passed the earlier Atomic Energy Act. 464 U.S. at 251-53.

Had it not been for this exceedingly unambiguous signal of congressional understanding, the case might well have come out differently. Justice White, writing for the majority, in fact stated that, "[T]his concern over the States' inability to formulate effective standards and the foreclosure of the States from conditioning the operation of nuclear plants on compliance with state-imposed safety standards arguably would disallow resort to state-law remedies by those suffering injuries from radiation in a nuclear plant." *Id.* at 250-51.

No comparable evidence of intent to allow tort actions can be found within the provisions of the Cigarette Act. The mere fact that some remedies which might otherwise be available to plaintiffs in state courts are removed is not, in and of itself, sufficient to require a rigid and inflexible application of the presumption against preemption where, as in the Cigarette Act, the statute itself so clearly

evinces Congress' legitimate aims. Furthermore, Petitioner and *amici* for Petitioner exaggerate the effect of preemption to the extent that they suggest that affirmance of *Cipollone* will strip consumers of all tort remedies for physical harm attributable to cigarettes. That is simply not so; only those claims that conflict with the objective of a unitary federal system of regulating the labeling, advertising, and promotion of cigarettes are preempted.

**(b) Congress Struck A Balance Between Economic And Health Goals In Drafting The Cigarette Act, And The States Are Not Free To "Improve" Upon That Balance Through Tort Rules.**

Petitioner's argument that tort actions further the purposes of the Cigarette Act rests on an idiosyncratic reading of the statute that distorts its purposes. Under this interpretation, the overriding goal of the Cigarette Act is to inform the public adequately about the health risks of smoking. Protection of commerce and of the national economy was merely an incidental, secondary consideration. Tort remedies for failure to warn, it is said, merely further Congress' purpose. *Carlisle v. Philip Morris, Inc.*, 805 S.W.2d 498, 510-11 (Tex. Ct. App. 1991); *Dewey v. R.J. Reynolds Tobacco Co.*, 121 N.J. 69, 87-88, 577 A.2d 1239, 1248 (1990).

The Act does say that Congress intended that the public be informed about health risks by means of labeling. But it also says that Congress intended to protect the national economy "to the *maximum* extent possible consistent with [the] declared policy" of the Act. Importantly, *Congress itself* decided how to accommodate the informational and economic values, and it did not invite the states to rework that balance according to their own predilections. Congress decided that the way to achieve both the economic and informational goals was to draft the specific warning message itself and to prohibit the states from establishing any other requirements. Thus, the Cigarette Act was not so predominantly a public health measure that courts are justified in jettisoning Congress' economic goals. Rather, the Act was a compromise over which Congress exercised plenary control. The "narrow" approach to public health taken by



the Act, reconciling public health goals with economic ones, has been acknowledged by courts for close to two and a half decades. *See Banzhaf v. Federal Communications Comm'n*, 405 F.2d 1082, 1090-91 & n.25 (D.C. Cir. 1968), *cert. denied*, 396 U.S. 842 (1969).

If, as *Carlisle* and *Dewey* seem to assume, Congress had intended to maximize the amount of health information cigarette manufacturers must make available to consumers each time they pick up a pack or look at an advertisement, the structure it adopted for the Cigarette Act was certainly an odd way to go about it. The only reasonable conclusion is that Congress did not have the objective that the *Carlisle* and *Dewey* courts, and Petitioner, have attributed to it.

**(c) State Tort Remedies Based On Failure To Warn Actually And Directly Conflict With The Operation Of The Cigarette Act.**

Petitioner's argument that no direct conflict exists between the Cigarette Act and state tort remedies for failure to warn is borrowed from *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). In a case involving the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 *et seq.*, the *Ferebee* court concluded that tort remedies for failure to warn did not conflict with the federally-mandated warnings because manufacturers could comply with both federal and state law by simultaneously using the federally-approved label and paying tort damages.

The *Ferebee* reasoning splits hairs in a fashion worthy of a medieval scholiast. The Court of Appeals for the First Circuit made short work of this argument in *Palmer v. Liggett Group, Inc.*, 825 F.2d 620 (1st Cir. 1987). Calling it "disingenuous," the court added:

> This 'choice of reaction' seems akin to the free choice of coming up for air after being underwater. Once a jury has found a label inadequate under state law, and the manufacturer

> liable for damages for negligently employing it, it is unthinkable that any manufacturer would not immediately take steps to minimize its exposure to continued liability. The most obvious change it can take, of course, is to change its label.

*Id.* at 627-28. The exercise by cigarette manufacturers of their "free choice" to change their labels in the face of a variety of state court decisions would, to be sure, totally defeat Congress' stated goal of protecting against "diverse, nonuniform, and confusing cigarette labeling and advertising regulations."

Petitioner's *amici* try to avoid this obvious problem with their argument in two ways. Some say that there need be no lack of uniformity because manufacturers can use in all states the version of the warning that would satisfy the most stringent of the varying state standards. Brief of the National League of Cities, *et al.*, at 26 & n. 20. Presumably, this would mean warning about every conceivable health effect of smoking, an approach which, whether or not it meets the test of uniformity for a given manufacturer, certainly fails miserably under the "nonconfusing" standard.[19] In addition, this approach would not address the problem of nonuniformity of warnings *among* manufacturers as each company tries to come up with its own response to the threat or reality of failure-to-warn suits.

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19 As a policy matter, furthermore, overly comprehensive warning messages can be counterproductive. Experts agree that "overwarning" can lead consumers to disregard information. *See, e.g.*, Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warnings in Products Liability – Design Defect Litigation Comes of Age*, 61 Cornell L. Rev. 495, 514 (1976); Schwartz & Driver, *Warnings in the Workplace: The Need for a Synthesis of Law and Communication Theory*, 52 U. Cin. L. Rev. 38, 60 (1983). This point was acknowledged recently by the Occupational Safety and Health Administration (OSHA). The amount of warning information on chemicals in the workplace should be minimized, said OSHA, because:

> This approach is in keeping with the Agency's evaluation of available data on effectiveness . . . which indicates that the more detail there is on a label, the less likely it is that employees will read and act on the information.

53 Fed. Reg. 29841 (1988). Petitioner's *amici* have not explained why product warnings should be controlled by the state whose law is the least consistent with sound communications theory, and the most disrespectful of Congress' intent to protect national commerce.



Others blithely suggest that the manufacturers can leave their label warnings alone and instead fulfill their common law duty to warn by package inserts, public service announcements, warning brochures, instruction manuals, and general educational programs. *See* Brief *Amicus Curiae* of the American Cancer Society *et al.* at 17; Brief *Amicus Curiae* of the Five Former Surgeons General *et al.* at 10-12. This argument is spurious; indeed no support for it is offered.

First, if state courts were free to require a variety of these alternative methods of warning, the goal of a uniform regulatory scheme for cigarette manufacturers would be defeated as surely as if courts were to require *ad hoc* amendments to the current federally mandated warnings on cigarette packs and in advertisements. Congress decided on the warnings manufacturers must give and on the places where they must give them. It did so to provide businesses with the benefit of a method they could depend on to meet their responsibility to consumers in a clear, nonconfusing way.[20] The suggestion of Petitioner's *amici* is no more or less than a clever attempt to accomplish an end run around Congress' objectives.

This observation has special pertinence to the suggestion that package inserts—rather than changes in the warnings *on* the packages—could be used to fulfill the common law requirements. Pack-

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20 To understand the business significance of a uniform regulatory scheme, the Court must take into account the uncertainties that currently attend a manufacturer's efforts to meet its common law duty to warn. Tort rules are applied on an *ad hoc* basis. As a result, one way businesses can respond is to change a product warning after each successful lawsuit. Not only are considerable expenses entailed in constant revisions of this sort, but the manufacturer must also decide what to do with products already in the stream of commerce. Do they need to be recalled? Must additional warnings be communicated as to them, and, if so, how? Alternatively, a manufacturer could respond by trying at the outset to devise the most comprehensive warning imaginable. This approach, however, may result, as already discussed, in an ineffective warning. Also, as a practical matter, it is virtually impossible to craft a warning, however comprehensive, that is certain to satisfy all courts and all juries. *See, e.g., MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, 71-72 (up to jury to decide whether the government-approved language chosen for the warning adequately alerted plaintiff to the risk of strokes from use of oral contraceptives), *cert. denied*, 474 U.S. 920 (1985). These are precisely the uncertainties a uniform statutory scheme avoids.

age inserts are merely another form of labeling.[21] To distinguish package inserts from what appears on the outside of the package, therefore, is a particularly sophistical attempt to defeat Congress' intent.

Furthermore, it is far from clear under the law of most states that the alternatives suggested by Petitioner's *amici* would in fact be deemed adequate alternatives to warnings on the cigarette pack itself. Public service announcements and educational programs may reinforce warnings on the product, but they have yet to be held to be a substitute for them. Cigarettes are not complex equipment like a car or a chain saw, and the suggestion that they be sold with instruction manuals or brochures is replete with so many practical problems as to be absurd on its face.

In any event, manufacturers have no assurance that state courts will find warnings that appear in places other than on the outside of the package a satisfactory way to meet their duty at common law. In many states, part of the calculus for the jury in deciding the adequacy of a warning is whether its placement is adequate.[22] Warnings are typically expected to be on the product itself or on its packaging, and liability may be imposed if the cautionary information appears solely in a booklet or is otherwise not placed directly on the product or its packaging.[23] For that reason, it is standard practice to advise manufacturers to place safety warnings directly on the product or package so that the information can be seen whenever the consumer uses it. Ross, *Legal and Practical Considerations for the*

21 *See, e.g., Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 964 (package inserts referred to as labeling), *modified*, 532 F. Supp. 211 (E.D. Wis. 1981); *Feldman v. Lederle Laboratories*, 234 N.J. Super. 559, 561 A.2d 288, 299 (App. Div. 1989) (same), *cert. granted*, 122 N.J. 348 (1990); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, 70 (same), *cert. denied*, 494 U.S. 920 (1985).

22 *See, e.g., Bickram v. Case I.H.*, 712 F. Supp. 18, 22 (E.D.N.Y. 1989) (applying New York law); *Pell v. Victor J. Andrew High School*, 123 Ill. App. 3d 423, 78 Ill. Dec. 739, 462 N.E.2d 858, 863 (1984); *Ilosky v. Michelin Tire Corp.*, 307 S.E.2d 603, 611 (W. Va. 1983).

23 *See, e.g., Gordon v. Niagara Machine & Tool Works*, 574 F.2d 1182, 1185-88 (5th Cir. 1978) (Mississippi) (warning solely in product literature inadequate); *Griggs v. Firestone Tire & Rubber Co.*, 513 F.2d 851 (8th Cir.) (Missouri) (same), *cert. denied*, 423 U.S. 865 (1975); *Ilosky*, 307 S.E.2d at 611 (same).



*Creation of Warning Labels and Instruction Books*, Prac. Law Inst. Litigation and Administrative Practice Course Handbook No. 379: Litigation 103, 116 (1989). As a result, no one can safely predict that the common law duty to warn can be met while leaving the labeling on the cigarette pack itself untouched.

In summary, if this Court reverses the Third Circuit, it will indeed pave the way for an actual conflict, and one of a very serious sort. Petitioner attempts to characterize this conflict merely as an acceptable "tension" between state and federal objectives. This is not "tension"; it is an outright pitched battle in which state authority, if permitted, would directly undercut the goals the Act was designed to achieve.[24]

Duty to warn cases are a particularly vexing area of products liability law. The difficulty in anticipating what future courts and juries will find to be inadequate makes sensible business decisions about product information hard to reach. With a mass-marketed product, the potential liability for an incorrect guess, particularly in light of the real risk of repeated punitive damage awards, could easily be crippling. Congress chose—clearly and unambiguously—to prevent health and safety information from becoming a vehicle for, in the words of the *Banzhaf* court, "compelling the cigarette companies to dig their own graves." 405 F.2d at 1090. This economic calculus could easily be undone by a formalistic "actual conflict" analysis that ignores the real-world implications of the industry's "choice of reactions."

## II. REVERSING THE THIRD CIRCUIT USING THE ANALYTICAL FRAMEWORK SUGGESTED BY PETITIONER WOULD RESULT IN FORECLOSING PREEMPTION CLAIMS UNDER NUMEROUS OTHER STATUTES

Given the strong evidence of congressional intent outlined above, it is scarcely surprising that, in all but two of the jurisdic-

24 As the discussion at pp. 13–16, *supra*, shows, the express preservation of common law remedies in the Smokeless Tobacco Act cannot be used to argue that the conflict between tort remedies and the goals of the Cigarette Act is a tension that Congress intended to tolerate in tobacco health warning legislation. Judge Mazzone's use of the Smokeless Tobacco Act for this purpose in *Palmer v. Liggett*

tions that have thus far considered the question, the prevailing rule is that duty to warn claims are indeed preempted. Petitioner urges this Court to disregard that strong consensus among state and federal courts. Furthermore, he urges the Court to reach that result by applying a rule that represents a serious misreading of existing law. The Court should find, Petitioner argues, that Congress cannot displace state tort remedies unless it either expresses its intent to do so "with drastic clarity" or there is no conceivable sense, however unsatisfactory, in which federal and state law can coexist.

This Court should clearly and firmly reject the invitation to adopt a rule that would exclude preemption except in cases where Congress makes its will known not only by explicitly addressing the *result* it seeks to achieve, but by detailing as well the means to that end. Certainly, that approach would not be consistent with established precedent. For example, in *International Paper Co. v. Ouellette*, a case in which a common law tort remedy was found to be preempted despite a broad savings clause, Justice Powell, writing for the majority, said flatly, "[I]t is not necessary for a federal statute to provide explicitly that particular state laws are preempted." 479 U.S. 481, 491 (1987). Instead, the Court has decided preemption questions by highly fact-specific inquiries into each piece of legislation and each particular alleged conflict. What the Court has sought to discern by careful examination of the purpose, structure, and language of the statute is whether Congress' intent to displace state law is made "clear and manifest." *English v. General Electric Co.*, 110 S. Ct. 2270, 2279 (1990).

"Clear and manifest" does not mean beyond a reasonable doubt. It does not mean that Congress must express its intent with absolute precision and in elaborate detail. The presumption against preemption, as historically applied, serves to accommodate the concerns of federalism while at the same time facilitating the operation of the Supremacy Clause. By suggesting that preemption should be found only where Congress speaks with "drastic clarity" or where no alternatives, however far-fetched, would allow state and federal

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*Group, Inc.*, 633 F. Supp. 1171, 1179 (D. Mass. 1986), *rev'd*, 825 F.2d 620 (1st Cir. 1987) altogether ignores the crucial differences between the two statutes that explain why tort remedies frustrate the purpose of one act but not the other.



law to coexist, Petitioner seeks to shift the underlying nature of that accommodation.

The reason for doing so in this case is far from clear. This is not, after all, a matter which implicates state sovereignty under the Eleventh Amendment; there a drastic clarity standard serves an intelligible structural purpose, rooted in the shape and language of the Constitution. This is a case solely implicating the exercise of power by Congress under the Commerce Clause. That an exercise of this power can displace state law should not be treated as a lamentable result to be avoided whenever possible, but rather the unremarkable outcome of the original constitutional decision to cede authority over interstate commerce to a federal legislative body and to back that authority with the weight of the Supremacy Clause.

Were the Court to pursue the path suggested by the Petitioner, it would work a structural change in this original agreement. The presumption against preemption would be elevated into an affirmative barrier, a stumbling block thrust by the judiciary onto the path Congress takes to effectuate its legitimate legislative goals. This would tip the balance in federal-state relations as sharply out of equilibrium as would a broad presumption in favor of preemption.

This Court's traditional practice of highly particularized treatment of preemption cases under the Commerce Clause recommends itself on pragmatic as well as theoretical grounds. As noted in an earlier section of this brief, Congress will rarely be able to foresee with unerring accuracy every development in state law that could result in a defeat or distortion of the goals of a federal law. The Cigarette Act, for example, was passed at a time when the law of products liability was in its infancy. Few would have predicted, we think, the complexities that now attach in various states to the common law duty to warn. It would be unrealistic and obstructive to require that Congress accommodate the unpredictable future by amending legislation to adapt to every relevant new tort rule.

A further benefit of the Court's careful, individualized analysis of preemption claims is that it avoids the inadvertent disposition of other cases. Should the Court, as we urge, affirm the Third Circuit in its usual fact-specific way, preemption claims arising under other statutory structures will not be prematurely decided. But if the Court

were to reverse the Third Circuit using the analytical scheme urged by Petitioner and his *amici*, the effect would be to automatically foreclose preemption claims by a wide range of manufacturers under numerous other statutes.

Untimely preclusion, of course, is precisely the result that Petitioner is urging. In his view, a sweeping "drastic clarity" rule would be a good thing, an effective way to put out what he characterizes perjoratively as a "prairie fire" of preemption. By this, he refers to litigation arising under a wide variety of statutes and affecting a broad range of American industry. These statutes have in common a goal of achieving a degree of nationwide uniformity in matters such as safety standards and product information. In addition to the Alcohol Act, discussed above, examples of statutes with preemption provisions are FIFRA, 7 U.S.C. § 136v; the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a); and the National Traffic and Motor Vehicle Safety Act, 15 U.S.C. § 1392(d). Other statutory schemes lack preemption provisions but have nevertheless presented questions of whether or not it is appropriate for states to regulate in the same area by means of their tort law. Requirements by the Food and Drug Administration for warning information on drugs are an example.

In some areas, for example FIFRA, the lower courts have divided on the preemption question.[25] In others, for example cases covered by the Medical Device Amendments, support for a finding of preemption has been essentially uniform, much as in the cigarette litigation.[26] In still other instances, for example those relating to

[25] *See, e.g., Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir. 1991) (state tort claims pre-empted), *petition for cert. filed*, 59 U.S.L.W. 3825 (U.S. May 29, 1991) (No. 90-1837); *Fisher v. Chevron Chem. Co.*, 716 F. Supp. 1283 (W.D. Mo. 1989) (same); *Fitzgerald v. Mallinckrodt, Inc.*, 681 F. Supp. 404 (E.D. Mich. 1987) (same); *but see Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir.) (no preemption), *cert. denied*, 469 U.S. 1062 (1984); *Cox v. Velsicol Chem. Corp.*, 704 F. Supp. 85 (E.D. Pa. 1989) (same); *Roberts v. Dow Chem. Co.*, 702 F. Supp. 195 (N.D. Ill. 1988) (same).

[26] *See, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989); *Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058 (D. Minn. 1989); *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475 (S.D. Ind. 1988); *Lavetter v. International Playtex*, 706 F. Supp. 722 (D. Ariz. 1988); *Stewart v. International Playtex, Inc.*, 672 F. Supp. 907 (D.S.C. 1987); *Berger v. Personal Products,*



regulation under the Food and Drug Act, claims have thus far been largely unsuccessful.[27]

We do not take a position on the merits of any of these preemption questions or on the validity of the existing precedent concerning these questions. They are not before the Court. Rather, we would like simply to point out that manufacturers, when they invoke a preemption defense under these federal statutes, are not behaving deviously or distorting the "benign" intentions of the law. Indeed, it would seem a quite reasonable *quid pro quo* for compliance with a national regulatory scheme that the regulated industry have the benefit of a set of instructions which, if followed, satisfy an industry's affirmative duties in the regulated area. It is not beyond belief that Congress could, in some if not all of the examples invoked by the Petitioner in his "parade of horribles," have intended just such a result. A rule of "drastic clarity" or a requirement of absolute conflict, either of which would deprive the Court of the ability to examine all the relevant evidence and make a reasoned judgment, could effectively decide the outcome of all these cases without regard to the purposes of Congress or its economic judgments. We urge the Court to avoid this draconian and unnecessary outcome.

*Inc.*, 115 Wash. 2d 267, 797 P.2d 1148 (1990), *cert. denied*, 111 S. Ct. 1584 (1991).

[27] *See, e.g., Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142 (D. Or. 1989) (state tort actions not pre-empted by federal regulation of intrauterine contraceptives); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, *cert. denied*, 474 U.S. 920 (1985) (tort action for duty to warn not preempted by federal labeling requirements).

## CONCLUSION

For the reasons stated above, the judgment of the Court of Appeals should be affirmed.

*Respectfully submitted,*

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## STATUTORY APPENDIX

**Federal Cigarette Labeling and Advertising Act: 15 U.S.C. § 1334**

(a) No statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package.

(b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

**Medical Device Amendments of 1976: 21 U.S.C. § 360k(a)**

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

**Alcoholic Beverage Labeling Act of 1988: 27 U.S.C. § 216**

No statement relating to alcoholic beverages and health, other than the statement required by section 215 of this title, shall be required under State law to be placed on any container of an alcoholic beverage, or on any box, carton, or other package, irrespective of the material from which made, that contains such a container.

**Alcoholic Beverage Labeling Act of 1988: 27 U.S.C. § 213**

The Congress finds that the American public should be informed about the health hazards that may result from the consumption or abuse of alcoholic beverages, and has determined that it would be beneficial to provide a clear,

nonconfusing reminder of such hazards, and that there is a need for national uniformity in such reminders in order to avoid the promulgation of incorrect or misleading information and to minimize burdens on interstate commerce. The Congress finds that requiring such reminders on all containers of alcoholic beverages is appropriate and necessary in view of the substantial role of the Federal Government in promoting the health and safety of the Nation's population. It is therefore the policy of the Congress, and the purpose of this subchapter, to exercise the full reach of the Federal Government's constitutional powers in order to establish a comprehensive Federal program, in connection with the manufacture and sale of alcoholic beverages in or affecting interstate commerce, to deal with the provision of warning or other information with respect to any relationship between the consumption or abuse of alcoholic beverages and health, so that—

(1) the public may be adequately reminded about any health hazards that may be associated with the consumption or abuse of alcoholic beverages through a nationally uniform, nonconfusing warning notice on each container of such beverages; and

(2) commerce and the national economy may be—

(A) protected to the maximum extent consistent with this declared policy,

(B) not impeded by diverse, nonuniform, and confusing requirements for warnings or other information on alcoholic beverage containers with respect to any relationship between the consumption or abuse of alcoholic beverages and health, and

(C) protected from the adverse effects that would result from a noncomprehensive program covering alcoholic beverage containers sold in interstate commerce, but not alcoholic beverage containers manufactured and sold within a single State.